UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

SKYLAR WILLIAMS, individually and on behalf of all others similarly situated, Plaintiff, v. GALDERMA LABORATORIES, L.P., Defendant.	Civil Case No. 1:24-cv-02222 Hon. Lindsay C. Jenkins

DEFENDANT GALDERMA LABORATORIES, L.P.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS

I. INTRODUCTION

Defendant Galderma's cream cleanser Differin is one of a number of topical acne treatments that contain benzoyl peroxide ("BPO") as their active ingredient and that have been widely used for some forty years. Also for decades, the U.S. Food and Drug Administration ("FDA") has approved these treatments as "safe and effective." As an over-the-counter ("OTC") acne product, Differin is subject to comprehensive FDA requirements that dictate its specific labeling and warnings and that preempt lawsuits like this one.

Plaintiff does not claim to be at increased risk of harm from Differin; instead she brings consumer protection and unjust enrichment claims on behalf of herself and two putative classes (an Illinois subclass and a multi-state subclass) based on Galderma's purported failure to disclose that BPO in OTC acne products degrades into benzene over time. While she asserts that benzene is a human carcinogen, Plaintiff claims ***only*** that she and other consumers overpaid for the product.

Plaintiff's claims fail as a matter of black letter law, because federal law expressly preempts them. The federal Food, Drug, and Cosmetic Act ("FDCA") prohibits claims based on purported requirements under state law that are "different from," "in addition to," or "otherwise not identical with" federal requirements. 21 U.S.C. § 379r(a). Requiring Galderma to add a benzene warning to Differin would cause the product to deviate from the federal labeling requirements. Nor can Plaintiff escape preemption by pleading parallel "misbranding" or "adulteration" claims. FDA's labeling requirements specifically state that topical acne products that comply with the requirements are ***not*** misbranded. Plaintiff similarly has no viable theory of adulteration—her allegation is not that a contaminant creeped into the product during manufacturing, but that BPO becomes benzene through "degrad[ation] over time." *See, e.g.*, Compl. ¶ 3. That is not adulteration.

For these and other reasons outlined below, the Court should dismiss the Complaint.[1]

II. BACKGROUND

A. Regulatory Background

FDA regulates the sale of OTC drug products in the United States. Various regulatory pathways govern approval of OTC products; the monograph process applies to topical acne products. 21 C.F.R. § 330.10. Monographs—detailed regulations for certain OTC products—set forth the FDA-approved active ingredients for a given therapeutic class and the labeling requirements for those drugs. *See id.*; *Nat. Res. Def. Council v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013) ("Like a recipe, each monograph sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is [generally recognized as safe and effective]."). An OTC drug that "fails to conform to an applicable monograph . . . is liable to regulatory action." 21 C.F.R. § 330.10(b).

In March 2010, FDA first announced that OTC acne treatments containing BPO are "generally recognized as safe and effective." 75 Fed. Reg. 9767 (Mar. 4, 2010); 21 C.F.R. § 333.301 (2023). FDA adopted the most recent monograph governing topical acne drug products in 2020. *See* U.S. Food & Drug Admin., Over-the-Counter Monograph (OTC) (M006), https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M006-Topical%20Acne%\20drug%20products%20for%20OTC%20Human%20Use%2011.23.2021.pdf (the

[1] "Prior to class certification, determining whether this Court has specific jurisdiction over Defendants with respect to the claims of the unnamed class members would be premature." *Jett v. Warrantech Corp.*, 436 F. Supp. 3d 1170, 1178 (S.D. Ill. 2020). Accordingly, Galderma reserves all rights to challenge the Court's exercise of personal jurisdiction over it with respect to any plaintiffs that are subsequently added to this lawsuit, including any representative plaintiffs.

"2020 Monograph").[2] The 2020 Monograph permits the formulation of topical acne products using benzoyl peroxide as the active pharmaceutical ingredient. *Id*. § 333.310(a). It also sets out comprehensive labeling requirements for OTC acne drug products, including naming, indications for use, and user directions. *Id*. § 333.350. There are specific warnings that BPO products must provide, none of which includes a reference to benzene. *Id*. Topical acne products that comply with the 2020 Monograph's conditions and the conditions listed in 21 C.F.R. § 330.1 are "generally recognized as safe and effective" and "[are] not misbranded." *Id*. § 333.301(a).

The conditions listed in 21 C.F.R. § 330.1 include labeling regulations applicable to all OTC drugs. 21 C.F.R. § 330.1. OTC drug labels must list the product's "active" and "inactive" ingredients. An "active ingredient" is "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans." *Id*. § 201.66(b)(2). An "[i]nactive ingredient" is "any component other than an active ingredient." *Id.* § 201.66(b)(3). A "component" is "any ingredient intended for use in the manufacture of a drug product." 21 C.F.R. § 210.3(b)(3).

B. Overview of the Litigation and Filing of the Complaint

On March 6, 2024, the online pharmacy Valisure LLC filed a citizen petition with FDA reporting that its testing of BPO acne products detected the presence of benzene. *See* https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide (last visited May 29, 2024). Valisure purports to operate independently, but its testing methodologies, including high-heat testing, have been debunked by both FDA and the courts. *See* Letter from

[2] The Court may take judicial notice of publicly available information on official government websites, *Denius v. Dunlap*, 330 F.3d 919, 926 (7th Cir. 2003), as well as documents "critical to a complaint and referred to in it," *Geinosky v. City of Chicago*, 675 F.3d 743, 746 n.1 (7th Cir. 2012), such as the Valisure citizen petition discussed *infra*.

FDA to Valisure (Dec. 5, 2022), https://www.fda.gov/media/163682/download (raising numerous concerns about Valisure's testing); *In re Zantac Prods. Liab. Litig*, 644 F. Supp. 3d 1075, 1091–94 (S.D. Fla. 2022) (describing Valisure's flawed methodology of measuring a purported carcinogen). Plaintiff's Complaint relies solely on the Valisure citizen petition for allegations about the purported "discovery of benzene" in BPO products. *See* Compl. ¶¶ 37–43. Valisure allegedly made the discovery by exposing 99 BPO-containing products to high levels of heat (37°C/98.6°F, 50°C/122°F, and 70°C/158°F) for sustained periods of time (two to three weeks), and then testing them for benzene. *Id.* ¶ 41. Valisure tested only one Galderma product: Differin 5% cleansing cream. *Id.* ¶ 42. To date, FDA has taken no action on Valisure's petition.

Benzene purportedly forms in these acne products because "BPO degrades over time, directly into benzene." *Id.* ¶ 1. According to the citizen petition, "***the specific problem with benzene in benzoyl peroxide products does not appear to be a contamination issue from a specific ingredient, but instead the inherent instability of the benzoyl peroxide molecule that breaks down and forms benzene***." *Id.* ¶ 43 (quoting citizen petition; emphasis in original). Benzene is alleged to form, not during manufacturing, but as "a natural and foreseeable result of the Product's distribution and handling." *Id.* ¶ 25. In other words, the Complaint does not allege contamination; it alleges a "defect" inherent in the product as BPO purportedly degrades over time.

Three days before filing this Complaint against Galderma, Plaintiff filed a putative class action lawsuit against Walmart that contains nearly the same claims and allegations. *See* Compl., *Williams v. Walmart, Inc.*, No. 1:24-cv-02173, ECF No. 1 (N.D. Ill. Mar. 15, 2024). Here, Plaintiff claims that Galderma's failure to disclose that Differin may contain benzene constitutes an actionable omission. *See, e.g.*, Compl. ¶¶ 4, 6–8. Asserting economic losses only, Plaintiff claims: (1) a violation of the Illinois Consumer Fraud and Deceptive Trade Practices Act (the "ICFA"),

815 ILCS 505/1, *et seq*., on behalf of herself and an Illinois subclass (Count I); (2) violations of the California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington consumer protection statutes, on behalf of herself and the multi-state subclass (Count III); and (3) unjust enrichment, on behalf of herself and the classes (Count II). Plaintiff points to no labeling requirements that Galderma violated. She alleges generally that benzene formed because of Galderma's failure to comply with cGMPs, *id.* ¶ 60, but she cites no cGMP that pertains to the degradation of BPO. *See e.g.*, *id.* ¶¶ 4, 25. Plaintiff does not allege that she or any of the absent class members suffered personal injury. *See id.* ¶¶ 92, 131, 136-138.

III. LEGAL STANDARD

To survive a Rule 12(b)(6) motion, a complaint must assert a facially plausible claim and provide fair notice to the defendant of the claim's basis. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." *Id.* Rather, "[t]o properly state a claim, a plaintiff's complaint must contain allegations that plausibly suggest that the plaintiff has a right to relief, raising that possibility above a speculative level." *Kubiak v. City of Chicago*, 810 F.3d 476, 480 (7th Cir. 2016).

IV. ARGUMENT

A. Federal Law Preempts Plaintiff's Claims

1. Plaintiff's Claims Are Expressly Preempted.

The Supremacy Clause of the U.S. Constitution provides that "the Laws of the United States . . . shall be the Supreme Law of the Land." U.S. Const. art. VI, cl. 2. Under this provision, "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Group, Inc.*, 505

U.S. 504, 516 (1992). Preemption of state law is express where Congress explicitly states such intention in the language of a statute. *FMC Corp. v. Holliday*, 498 U.S. 52, 56–57 (1990).

Finding that the interest in national uniformity and federal oversight of pharmaceutical products is paramount, Congress has explicitly mandated that federal law preempts nearly all state law claims relating to OTC medications. *See* 21 U.S.C. § 379r(a). Specifically, consumers may not bring any state law claims that would impose duties on companies marketing OTC products that are "different from," "in addition to," or "otherwise not identical with" a federal requirement under the FDCA. 21 U.S.C. § 379r(a). Section 379r exempts only one discrete category of claims—those brought "under the product liability law of any State"—from its express preemption mandate. 21 U.S.C. § 379r(e). There is no product liability claim here.

Section 379r's preemption mandate is accordingly broad: it preempts ***any*** state law requirement related to an OTC drug that is ***not identical*** to federal requirements, as well as common law duties imposed through civil damages that differ from or add to federal requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324–25 (2008). The FDCA, the federal regulations governing acne BPO products, and the 2020 Monograph all constitute federal "requirements" for purposes of Section 379r preemption. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 793–95 (2002) (final monograph regulating OTC head lice products established federal "requirement[]"); *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 785–87 (E.D. Tex. 2008) (the "approved monograph for pediculicides . . . establishes a federal requirement with respect to drug labeling under the FDCA"). Plaintiff's claims here are expressly preempted because they seek to impose obligations that differ from those that FDA has imposed in finding that BPO products are safe and effective when labeled in compliance with federal requirements.

Courts have repeatedly found that Section 379r preempts analogous claims. *Truss v. Bayer Healthcare Pharmaceuticals*, No. 21 CV 9845 (VB), 2022 WL 16951538, at *4 (S.D.N.Y. Nov. 15, 2022), for example, is on all fours. In *Truss*, the plaintiffs alleged that the defendants should have disclosed the presence of benzophenone—"a hazardous impurity and degradation product of octocrylene, which is an active ingredient in the Product"—in the product labeling. *Id*. at *4 (internal quotations and citation omitted). The court disagreed, concluding that no federal requirement obligated the defendant to make such a disclosure. Instead, FDA's monograph governing sunscreen products "allows sunscreens to be formulated with the active ingredient [octocrylene], and does not require disclosure that octocrylene may degrade into benzophenone." *Id*. The court accordingly dismissed plaintiffs' state law claims as preempted. *Id*.

Courts in the Seventh Circuit have reached similar conclusions. In *Harris v. Topco Associates*, 538 F. Supp. 3d 826 (N.D. Ill. 2021), the plaintiffs filed consumer protection claims against the manufacturer of OTC acetaminophen products, alleging that the company should have disclosed that there was "no pharmacological distinction between [the] Infant's Product and [the] Children's Product." *Id.* at 832. The court looked to the applicable monograph and found that it did "not require any specific disclaimers concerning infant products nor the interchangeability of the two products at issue." *Id*. at 833. The court accordingly dismissed the plaintiffs' claims as preempted: "Harris' claims are preempted because she seeks to impose additional obligations on Topco not imposed by the [monograph]." *Id.*; *see also Turek v. Gen. Mills, Inc.,* 662 F.3d 423, 427 (7th Cir. 2011) ("The disclaimers that the plaintiff wants added to the labeling of the defendants' inulin-containing chewy bars are not identical to the labeling requirements imposed on such products by federal law, and so they are barred.").

Section 379r's "savings clause" (subsection e) does not save Plaintiff's claims, because that clause is limited to product liability claims, and Plaintiff here asserts no such claims. Federal common law defines "product liability" as alleged physical and property harms derived from operation of the product, not claims for refund of the purchase price. *See Home Warranty Corp. v. Caldwell*, 777 F.2d 1455, 1457–62, 1486 (11th Cir. 1985) (canvassing the history of "products liability" law and explaining "[i]t is a traditional concept of products liability law that the products liability risk does not include the loss of or damage to the product itself."); 26 C.F.R. § 1.172-13(b)(2)(i) (defining "product liability" to "mean[ ] the liability . . . for damages resulting from physical injury or emotional harm to individuals, or damage to or loss of the use of property").

Plaintiff seeks a refund of the purchase price of Differin. *See* Compl. ¶¶ 92, 131, 136-138. Because Plaintiff does not bring claims for personal injury or property damage, the "product liability" exception does not apply *See Mills*, 581 F. Supp. 2d at 793 (plaintiffs' claims for economic damages "are not products liability actions" and so "not 'saved' from preemption"); *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 512 F. Supp. 3d 1278, 1300 (S.D. Fla. 2021) ("any claim for a refund for the purchase of OTC ranitidine products that is premised upon the allegation that Plaintiffs suffered no personal injury . . . is not saved under the § 379r savings clause").

2. Plaintiff Has Not Adequately Alleged a Parallel Misbranding or Adulteration Claim

The Supreme Court has held that parallel claims—that is, state law claims premised on a violation of federal law—are not expressly preempted because such claims are not in conflict with federal requirements. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996) (recognizing remedies for violations of common law duties when those duties "parallel federal requirements"). Plaintiff seeks to avoid preemption by alleging parallel claims premised on violations of FDA regulations—i.e., regulations that prohibit a drug from being "misbranded" or "adulterated." *See* Compl. ¶ 52;

21 U.S.C. § 331(a), (b). A drug is misbranded "[i]f its labeling is false or misleading in any particular." 21 U.S.C. 352(a)(1). A drug is adulterated in relevant part if "[the] drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice." 21 U.S.C. § 351(a)(1); *see* Compl. ¶ 60. Neither applies here.

Plaintiff alleges that Differin is "misbranded" because the product's labeling "does not disclose the presence of benzene," rendering that labeling "false" and "misleading." *Id.* ¶ 61. This argument "rests on a mistaken premise . . . . With respect to the labeling of OTC drugs . . . it is not up to private litigants—or judges—to decide what is false or misleading. It is up to the FDA." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014). Here, FDA explicitly recognizes that topical acne products such as Differin "[are] not misbranded" so long as they comply with the 2020 Monograph's conditions and the general conditions listed in 21 C.F.R. § 330.1. 21 C.F.R. § 333.301(a). As neither the 2020 Monograph nor any other FDA labeling regulation requires Galderma to include a benzene warning on the product's label, Differin is not and cannot be misbranded for failing to include such a warning. *See supra* at p. 3.

Nor was Differin misbranded because its labeling did not list benzene as an "ingredient." *See, e.g.*, Compl. ¶¶ 4, 6, 44–46. Benzene does not qualify as an active or inactive ingredient, which by definition under the federal regulations are substances "intended" to be included in the drug product. *See* 21 C.F.R. §§ 201.66(b)(2), (b)(3); 21 C.F.R. § 210.3(b)(3). To the contrary, the Complaint alleges that "[t]hese products are not designed to contain benzene." Compl. ¶ 2. *See Truss*, 2022 WL 16951538 at *4 (because plaintiffs "[did] not allege defendants manufactured the Product to contain benzophenone," "benzophenone is not an active or inactive ingredient in the Product . . . and federal law does not require it to appear on the Product's label").

Plaintiff's allegations that Differin was "adulterated" fare no better. Her entire theory of the case has nothing to do with purported manufacturing lapses—on the contrary, her theory is that BPO "degrades over time to directly form benzene." *Id*. ¶ 40; *see also id.* ¶¶ 24–25 (showing the chemical structure of BPO and alleging that BPO "thermally decompose[s]" to form benzene). This theory of benzene formation is fundamentally inconsistent with the concept of adulteration.

The court in *In re Zantac(Ranitidine) Products Liability Litigation*, 20-MD-2924, 2023 WL 4765409 (S.D. Fla. July 26, 2023), recently addressed this very issue. There, the plaintiffs argued that the drug ranitidine was adulterated because it "breaks down into NDMA because of its inherent molecular design." *Id.* at 11. The court rejected this argument because of the fundamental flaw in the premise: "The Plaintiffs cannot state adulteration claims under the FDCA because they have proceeded in this MDL on the grounds that ranitidine self-adulterates. . . . Stated simply, the Defendants did not contaminate ranitidine with NDMA by including NDMA in the manufacturing process—ranitidine contaminated itself by the nature of its very design." *Id.* The court accordingly rejected the plaintiffs' request to amend their complaint to add an adulteration theory. *Id.* at *10. This same rationale dooms Plaintiff's adulteration claim here.

While the Court need look no further to dispose of Plaintiff's adulteration theory, the claim separately fails because it rests on *ipso facto* reasoning: that the "mere presence of benzene . . . resulted from Defendant's failure to comply with cGMPs." *See* Compl. ¶ 60. But Plaintiff never explains how Galderma allegedly failed to comply with any cGMPs. While she cites a few cGMPs, *see id*. ¶¶ 52-55, she does not actually allege that Galderma failed to comply with any of those provisions. She does not allege that Galderma failed (1) to maintain written procedures for production and process control; (2) to establish scientifically sound specifications, sampling plans, and test procedures, or (3) to maintain data derived from testing. *See generally id*.

To be sure, the Seventh Circuit has recognized that in certain circumstances allegations of cGMPs may give rise to a parallel claim—but such a claim is still subject to the *Twombly*/*Iqbal* pleading standard. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (2010) (citing *Twombly* and *Iqbal*). In *Bausch*, for example, the complaint survived dismissal where the plaintiff did not merely reference cGMPs in the abstract, as Plaintiff does here; the plaintiff cited to a specific FDA finding that the products at issue "were adulterated as a result of problems in the manufacturing process." *Id.* at 561. There is no such FDA finding here. *See also Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012) (citing *Bausch*, inter alia, for the proposition that "[t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs, but rather the existence of a manufacturing defect caused by a violation of federal regulations ***and*** allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury") (emphasis in original).

B. Plaintiff's Consumer Protection Claims Are Precluded or Inadequately Pled

1. Safe Harbor Provisions Bar Plaintiff's Claims

The ICFA's safe harbor provision forecloses non-personal-injury claims predicated on "[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." 815 ILCS 505/10b(1). As the Seventh Circuit has explained, the ICFA "will not impose higher disclosure requirements on parties than those that are sufficient to satisfy federal regulations." *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001); *Toulon v. Cont'l Cas. Co.,* No. 15 CV 138, 2015 WL 4932255, at *5 (N.D. Ill. Aug. 18, 2015) ("Where the fraud was a failure to make additional disclosures, a defendant's full compliance with applicable disclosure requirements constitutes a full defense."). Controlling federal law expressly authorizes Galderma to sell Differin without any

disclosure regarding the presence or potential presence of benzene. *See supra* at p. 3. The ICFA's safe harbor provision accordingly precludes Plaintiff's ICFA claim.

With the exception of Minnesota, the other state consumer protection laws at issue in this lawsuit similarly have safe harbor provisions for actions that comply with, or are authorized by, federal standards, or have adopted such a safe harbor as a matter of interpretation:

- **California**: California courts interpreting the Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq*.) have held that where "the Legislature has permitted certain conduct or considered a situation and concluded no action should lie, courts may not override that determination[.]" *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co*., 973 P.2d 527, 541 (Cal. 1999).

- **Florida:** The Florida Deceptive and Unfair Practices Act exempts "[a]n act or practice required or specifically permitted by federal or state law." Fla. Stat. § 501.212(1).

- **Massachusetts:** Massachusetts' statute exempts "transactions or actions otherwise permitted under laws as administered by [a U.S.] regulatory board or officer acting under statutory authority of . . . the United States." Mass. Gen. Laws Ann. Ch. 93A, § 3.

- **Michigan:** Michigan's statute exempts "[a] transaction or conduct specifically authorized under laws administered by a [U.S.] regulatory board or officer acting under statutory authority of . . . the United States." Mich. Comp. Laws § 445.904(1)(a).

- **Missouri:** Courts applying Missouri law have recognized a safe harbor under the Missouri Merchandising Practices Act, Mo. Stat. §§ 407.020, *et seq.*, where the transaction at issue is "expressly allow[ed]—and extensively regulate[d]." *Johnson v. MFA Petrol. Co.*, 10 F. Supp. 3d 982, 997 (W.D. Mo. 2014).

- **New Jersey:** Under New Jersey law, failure-to-warn claims based on marketing "subject to FDA oversight" are "not actionable." *N.J. Citizen Action v. Schering-Plough Corp*., 842 A.2d 174, 176 (N.J. Super. App. Div. 2003).

- **New York:** New York's statute provides a "complete defense" with respect to any "act or practice [that] is . . . subject to and complies with the rules and regulations of, and the statutes administered by . . . any . . . agency of the United States." N.Y. Gen. Bus. Law § 349(d).

- **Washington:** Washington's Unfair Business Practices-Consumer Protection Act exempts "actions or transactions otherwise permitted, prohibited or regulated under laws administered by [a U.S.] regulatory body." Wash. Rev. Code Ann. § 19.86.170.

Plaintiff's claims under these other state statutes thus fail for the same reasons as the ICFA claim.

2. Plaintiff Has Not Adequately Alleged the Knowledge Requirement of Her ICFA Claim

In a deceptive omissions case brought under the ICFA, a defendant can be liable only for failing to disclose a fact that it ***knew***. *See Castaneda v. Amazon.com, Inc*., 679 F. Supp. 3d 739, 752 (N.D. Ill. 2023) ("Knowledge is an essential part of any deception-based claim about an omission."); *Schwebe v. AGC Flat Glass N. Am., Inc*., No. 12 C 9873, 2013 WL 2151551, at *5 (N.D. Ill. May 16, 2013) ("in a case of fraud by omission, one would have to have knowledge of the fact at issue in order to be able to conceal it" (citing *Rockford Mem'l Hosp. v. Havrilesko*, 858 N.E.2d 56, 62-63 (Ill. App. Ct. 2006)). Plaintiff's Complaint lacks any adequately pleaded allegation of knowledge.

Plaintiff alleges, "[o]n information and belief," that Galderma "was aware of the degradation issues associated with [BPO]" because the "harms associated with [BPO] were known within scientific literature and was [*sic*] likely disclosed to Defendant when it sourced its [BPO]." Compl. ¶ 27. But Plaintiff has not pleaded that Galderma actually ***knew*** of this "scientific literature." *Id*. And she pleads no facts in support of her conclusory and speculative assertion that the alleged "degradation issues" were "likely disclosed" to Galderma when sourcing its product.

Moreover, these allegations are in fundamental tension with Plaintiff's assertions elsewhere that Valisure "***discover[ed]*** [ ] benzoyl peroxide's fundamental instability" through testing that was published in March of this year. *Id*. ¶ 40 (emphasis added). A core theory of Plaintiff's Complaint is that Galderma allegedly failed to conduct adequate testing, which would have revealed the purported problem. *See, e.g.*, *id*. ¶ 77 ("had [Defendant] fulfilled their quality assurance obligations, Defendant would have identified the presence of benzene through routine and required testing."). The allegations that Galderma "failed to detect" benzene, *id*. ¶ 6, undermine any suggestion that Galderma knew that BPO in Differin could degrade into benzene.

Because Plaintiff has failed to plead the factual predicate for the essential element of knowledge, her ICFA claim must be dismissed. *See, e.g.*, *Ibarolla v. Nutrex Rsch., Inc.*, No. 12 C 4848, 2013 WL 672508, at *4 (N.D. Ill. Feb. 25, 2013) ("We would cross the line into speculation if we took the step of inferring that either Defendant had actual knowledge of the dangers of DMAA before receiving the Warning Letter. Plaintiff has not alleged sufficient facts to support that inference. Therefore, Plaintiff has failed to state a claim for fraudulent concealment."); *White v. DaimlerChrysler Corp.*, 856 N.E.2d 542, 549 (Ill. App. Ct. 2006) (dismissing ICFA claim where plaintiff did "not specify how defendant knew this information" about a purported defect).

3. Because Plaintiff's ICFA Claim Fails as a Matter of Law, Her Consumer Sub-Class Claims Must Also Be Dismissed

Because Plaintiff has not and cannot state a claim under the ICFA, *see supra* at pp. 11–14, she cannot represent a multi-state class under other states' consumer protection laws, and Count III must accordingly be dismissed. *See, e.g.*, *Halperin v. Int'l Web Servs., LLC*, 123 F. Supp. 3d 999, 1009 (N.D. Ill. 2015) (dismissing multi-state class claim brought pursuant to nine state consumer protection laws because plaintiff's Illinois consumer protection claim failed to satisfy Rule 9(b)'s pleading requirements: "because Halperin has not adequately pleaded a consumer fraud claim under Illinois law . . . he cannot represent either an Illinois class under the ICFA or a multi-state class under the other nine States' consumer fraud laws"); *Van Zealand v. Rand McNally,* 532 F. Supp. 3d 557, 568–72 (N.D. Ill. 2021) (similar).

4. Plaintiff's Massachusetts' Consumer Protection Claim Fails for the Additional Reason that She Failed to Provide the Required Pre-Suit Notice

Massachusetts' consumer protection statute requires a claimant to provide "a written demand for relief" at least "thirty days prior to the filing of any such action." Mass. Gen. Laws ch. 93A, § 9(3). The only exemption to this pre-suit notice requirement is if 'the prospective respondent does not maintain a place of business . . . within [Massachusetts].'" *Woods v. Wells*

Fargo Bank, N.A., 733 F.3d 349, 359 (1st Cir. 2013) (internal citations and quotations omitted). Here, Galderma does maintain a place of business within Massachusetts. *See* Ex. A.[3] Plaintiff failed to provide Galderma with pre-suit notice as required, and her Massachusetts' consumer protection claim must be dismissed for this reason alone. *See, e.g.*, *Jones v. Bank of N.Y.*, 542 F. Supp. 3d 44, 57-59 (D. Mass. 2021) (holding that plaintiff failed to state a claim under Chapter 93A because, *inter alia*, he failed to provide pre-suit notice); *Woods*, 733 F.3d at 359 (similar).

C. Plaintiff's Unjust Enrichment Claim Fails

Plaintiff's unjust enrichment claim is based on the exact same allegations that underlie her consumer protection claims. *See, e.g.*, Compl. ¶¶ 135-138 (seeking recovery of "monies paid to purchase" Differin). Because Plaintiff's consumer protections claims fail, her unjust enrichment claim must, too, be dismissed. *See, e.g.*, *Cleary v. Philip Morris Inc.*, 656 F.3d 511, 518 (7th Cir. 2011) ("[I]f an unjust enrichment claim rests on the same improper conduct alleged in another claim, then the unjust enrichment claim will be tied to this related claim—and, of course, unjust enrichment will stand or fall with the related claim.").

V. CONCLUSION

For the foregoing reasons, Galderma requests that the Court dismiss Plaintiff's Complaint in its entirety and with prejudice.

[3] "A court may take judicial notice of documents in the public record when ruling on a motion to dismiss under Rule 12(b)(6)," such as documents filed with state Secretaries of State. *Harrow Indus. LLC v. Nexus Corp.*, No. 3:17-CV-3222, 2018 WL 1020114, at *2 (C.D. Ill. Feb. 22, 2018).

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Respectfully submitted,

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Attorneys for Defendant
Galderma Laboratories, L.P.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 30, 2024, the foregoing document was electronically filed with the Clerk of Court for the Northern District of Illinois through the Court's CM/ECF system, which will send a notice of electronic filing to all counsel of record.

Dated: May 30, 2024

/s/ Anand Agneshwar
Anand Agneshwar

EXHIBIT A

F

The Commonwealth of Massachusetts

William Francis Galvin
Secretary of the Commonwealth
One Ashburton Place - Room 1717, Boston, Massachusetts 02108-1512

Foreign Limited Partnership
Application for Registration
(General Laws Chapter 109, Section 49)

(1) The exact name of the limited partnership:

GALDERMA LABORATORIES, L.P.

(2) If different, the name under which it proposes to do business in the Commonwealth:

GALDERMA LABORATORIES, LIMITED PARTNERSHIP

(3) The jurisdiction where the partnership was organized:

TX

(4) The date of organization: 11/12/1999

(5) The general character of the business in the Commonwealth:

Commercial and economic activity

(6) The business address of its principal office:

2001 Ross Avenue
Suite 1600
Dallas TX 75201
United States

(7) The names, business addresses and residence address of its general partners:

NAME	ADDRESS
GALDERMA GENERAL LLC	1012 College Road Suite 201 Dover (Kent) DE 19904 2001 Ross Avenue Suite 1600 Dallas TX 75201

(8) The business address of its principal office in the Commonwealth, if any:

One Marina Park Drive, Suite 700, Boston, Massachusetts 02127

(9) The name and street address of its resident agent in the Commonwealth:

NAME	ADDRESS
CCS Global Solutions, Inc.	44 School Street, Suite 505 Boston, MA 02108

(10) The address of the office at which it keeps a list of the names and addresses of the limited partners and their capital contributions. The limited partnership agrees to keep those records until its registration in the Commonwealth is cancelled.

2001 Ross Avenue, Suite 1600, Dallas TX 75201

Signed *(by at least one general partner)*: DocuSigned by: 6AF8447F66A0461...

Consent of resident agent:

I CCS Global Solutions, Inc Joseph Pope-President

resident agent of the above limited partnership, consent to my appointment as resident agent pursuant to 6h c109 Section 52*

**or attach registered agents consent hereto.*

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate Of Limited Partnership for GALDERMA LABORATORIES, L.P. (file number 12668610), a Domestic Limited Partnership (LP), was filed in this office on November 12, 1999.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on October 23, 2023.

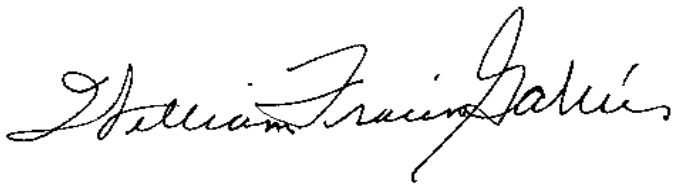
Jane Nelson
Secretary of State

MA SOC Filing Number: 202325625810 Date: 11/6/2023 10:32:09 AM

THE COMMONWEALTH OF MASSACHUSETTS

I hereby certify that, upon examination of this document, duly submitted to me, it appears that the provisions of the General Laws relative to corporations have been complied with, and I hereby approve said articles; and the filing fee having been paid, said articles are deemed to have been filed with me on:

November 06, 2023 10:32 AM



WILLIAM FRANCIS GALVIN

Secretary of the Commonwealth